REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of Claims

Claims 1, 2, and 4-12 are now pending and being examined on the merits.

II. Declaration

The examiner objects to the declaration as containing changes in the post office address of inventor that are not initialed. Accordingly, the examiner requires Applicants to file a new declaration.

A newly executed declaration has not yet been obtained. However, Applicants will submit a new declaration shortly.

III. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 1, 2, and 4-12 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The examiner argues that "the specification, while being enabling for a formulation comprising a hybridoma, said hybridoma comprising a DC and a tumor cell, does not reasonably provide enablement for a formulation comprising a hybridoma, said hybridoma comprising a DC and a virally infected cell." Office action at 2. Applicants respectfully traverse this ground of rejection.

The specification provides sufficient guidance to both make and use the claimed invention without undue experimentation, as discussed below.

A. The Specification Teaches How To Make The Claimed Invention

The specification teaches that "the hybridomas ... of the present invention can be formed by any method known in the art" (page 8, lines 3-4). The specification goes on to provide one method of forming an APC-virally infected cell using polyethylene glycol (PEG) (page 8, lines 4-11). Moreover, the specification contains working examples demonstrating the formation of a hybridoma (page 11, lines 5-19). Thus, the specification provides guidance as to how to construct the claimed formulation.

The Office Action argues that "simply stating that the hybridoma comprises 'a physical combination of at least two different cell types' and that said hybridoma can be made by 'any method known in the art', including PEG, does not comprise an enabling disclosure" (Office Action at 4). According to the Office Action, the hybridoma must be an immortal cell (Office Action at 3).

However, the specification does not require the hybridoma to be an immortal cell. "An applicant is entitled to be his or her own lexicographer," and "[w]here an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." MPEP § 2111.01(III). Here, the specification defines a hybridoma as "a physical combination of at least two different cell types" (page 6, lines 14-15). The specification further specifies that the two different cell types can be "at least one APC and at least one virally infected cell" (page 6, lines 15-18). Nothing in the specification requires the "hybridoma" to be an immortal cell. Thus, it is improper to require enablement of an immortal "hybridoma" even assuming *arguendo* that one of skill in the art understands a "hybridoma" to be an immortal cell.

In addition, there is no evidence or explanation to establish that one of skill in the art could not make a physical combination of an antigen presenting cell selected and a virally infected cell without undue experimentation. Indeed, such physical combinations were routine to one of skill in the art.

B. The Specification Teaches How To Use the Claimed Invention

The Office Action contends that undue experimentation is required to practice the claimed invention, because "the formulations of the instant claims would be more likely to exacerbate viral infections than to treat or prevent them." Office action at 3. As support for this contention, the Office Action cites references relating to HIV.

Contrary to the Office Action's assertions, one of skill in the art would be able to use the claimed formulations and compositions without undue experimentation. Marañón *et al.*, PNAS 101(16):6092:97 (2004) verifies the enablement of the claimed invention, as discussed in Applicants' Amendment of November 7, 2006. Briefly, Marañón studied the presentation of HIV antigens from dendritic cells and concluded that dendritic cell antigen presentation could be "exploited to eradicate latently infected reservoirs" (Marañón, abstract, emphasis added).

The Office Action argues that Marañón "cannot be used to establish the enablement of the instant application as of its priority date," because it was published "seven years after the priority date of the instant application" (Office Action at 4). In addition, the Office Action argues that Marañón "employs live antigen-loaded dendritic cells and not the fusion products of the instant claims" and that Marañón "addresses a number of issues that were clearly not known as of the priority date of the instant application." Office Action at 4.

However, these reasons for discounting Marañón are inapposite to Marañón's value in demonstrating the enablement of the claimed invention. Marañón employed the same general approach as claimed by Applicants and demonstrated the success of such an approach. Specifically, dendritic cells were co-cultured with virally-infected $CD4^+$ T lymphocytes, and the resulting antigen-presenting dendritic cells could be "exploited to eradicate latently infected reservoirs" (Marañón, abstract). The fact that Marañón was published after the priority date of the present application is of no consequence, because Marañón does not disclose techniques or insights absent from the present specification that are essential to practice the claimed invention. Similarly, Marañón's discussion of issues allegedly not known as of the priority date, such as

"the manner in which dendritic cells take up and present antigens" is not relevant to Marañón's value, because these insights are not necessary to make and use the claimed invention. Indeed, there is no evidence suggesting that the results obtained from using fusion products would differ from results obtained using Marañón's co-culture cells.

The examiner also argues that the claims are not enabled, because not every viral infection can be treated by the claimed invention. Office Action at 4-5. However, even assuming *arguendo* that not every viral infection can be treated using the claimed invention, "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled." MPEP § 2164.08(b). Here, one of skill in the art could easily determine which viral infections, if not all, could be treated using the claimed invention through simple screening. Such simple screening does not amount to undue experimentation. *See* MPEP § 2164.01.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

IV. Claim Rejections — Double Patenting

Claims 1, 2, and 4-12 stand provisionally rejected as allegedly being unpatentable over claims 1, 2, and 4-12 of copending Application No. 11/089,035 (Atty. Dkt. No. 076333-0366). The Examiner argues that "the claims of the '025 application recite a formulation and pharmaceutical composition comprising a hybridoma having an antigen presenting cell fused to a virally infected cell or a tumor cell."

Applicants note the provisional nature of this rejection and will address the rejection should it ever mature into a non-provisional rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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